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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,543	10/13/2004	Kjell Olmarker	003301-175	1315

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BUCHANAN, INGERSOLL & ROONEY PC  
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EXAMINER
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PROUTY, REBECCA E

ART UNIT	PAPER NUMBER
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1652

NOTIFICATION DATE	DELIVERY MODE
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09/03/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/506,543	<b>Applicant(s)</b> OLMARKER, KJELL	
	<b>Examiner</b> Rebecca E. Prouty	<b>Art Unit</b> 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2008 and 03 March 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 46 and 49-57 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 46 and 49-57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/09</u> .  | 6) <input type="checkbox"/> Other: _____                          |

Claims 1-45, 47, and 48 have been canceled. Claims 46, 49-56 and new claim 57 are at issue and are present for examination.

Applicant's election with traverse of Group XXIV drawn to methods of treating a wound comprising administering the peptide of SEQ ID NO:89 in the reply filed on 3/3/09 is acknowledged. The traversal is on the ground(s) that the examiner has not explained why the claims as amended are anticipated or obvious over the cited art. This is not found persuasive because the specific peptides recited in the instant claims are NOT a shared technical feature of the groups recited in the restriction requirement. Each specific peptide is a distinct technical feature and each recited group includes a different one. Thus none of these peptides is a shared technical feature. The only shared technical feature among all the groups is as recited in the restriction requirement, i.e., a method of treating a wound or improving wound healing comprising administering a peptide comprising a peptide derived from amino acids 12-40 of human lactoferrin (i.e., the generic invention that was previously claimed prior to the amendment). The Office has clearly explained why this generic concept is not novel and non-obvious in the previous Office Action. Thus the recited groups of the

amended claims do NOT share any special technical feature as defined by PCT Rule 13.2 and restriction is proper.

The requirement is still deemed proper and is therefore made FINAL.

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows: the instant application shares no inventor in common with prior application 10/092,919.

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: it claims priority under 35 USC 119 or 365(a) to a application which was not filed in a foreign country (i.e., US 10/092,919). It is noted that any claim to priority to this application should be made under 35 USC 365(c). However, it is noted that a proper claim to priority under 35 USC 365(c) requires that the requirements of 35 USC 120 be met but as discussed above these are not met for the instant situation as the prior application

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does not have an inventor in common with the instant application.

Claims 46 and 49-57 are objected to for including non-elected subject matter.

Claims 46 and 57 are objected to because of the following informalities: the recitation of "peptide derived from amino acid 12 to amino acid 40 of human lactoferrin" in claim 46 and "peptide derived from amino acid 20 to amino acid 31 of human lactoferrin" in claim 57 are unclear as explained in the previous Office Action although the scope of the instant claims themselves is not unclear in view of the recitation of specific peptide structures in the remainder of these claims. As such these recitations appear to have no meaning in the claim and are objected to. Appropriate correction is required.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a),

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the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 46 and 49-57 rejected under 35 U.S.C. 103(a) as being unpatentable over Meyer-Ingold et al. (US Patent 6,156,334) and Mita et al. (US Patent 5,561,109) in view of Hanson et al. (WO 00/01730).

Meyer-Ingold et al. and Mita et al. each teach the use of lactoferrin for the treatment of wounds (see particularly column 1 and claim 1 of Mita et al. and column 6, line 64 - column 7 line 18 of Meyer-Ingold et al.) due to their anti-bacterial activity.

Hanson et al. teach peptide variants of lactoferrin amino acids 12-40 and particularly amino acids 20-31, of human lactoferrin and that these peptides have use for the same purposes as lactoferrin, including particularly for treating infections. Hanson et al. teach that the peptides can be

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administered topically or systemically and particularly teach the peptide of SEQ ID NO:89.

Therefore, it would have been obvious to use the peptides of Hanson et al. for treating wounds as taught by Meyer-Ingold et al. and Mita et al. as Hanson et al. teach the use of these peptides for the same purposes as the lactoferrin taught by Meyer-Ingold et al. and Mita et al.. Furthermore, as bacterial infection is an undesirable complication of all wounds, it would have been obvious to one of ordinary skill in the art to used these peptides for the treatment of any type of wound including those cause by trauma, surgery, metabolic processes due to reduced nutritional supply, ulcer, or exposure to toxic compounds.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 46 and 49-57 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of copending Application No. 12/191,474. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 46 and 49-57 herein and claims 1-10 of copending Application No. 12/191,474 are both directed to methods of administering the peptide of SEQ ID NO:89 and other lactoferrin derivatives. The claims only in the recited effect of the method, however as the active steps recited are identical, the recited effects are inherent and the methods of the copending application anticipate the methods of the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS**



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**ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca E. Prouty whose telephone number is 571-272-0937. The examiner can normally be reached on Tuesday-Friday from 8 AM to 5 PM. The examiner can also be reached on alternate Mondays

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached at (571) 272-0811. The fax phone number for this Group is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system,

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see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rebecca Prouty/  
Primary Examiner  
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